

REMARKS

The present application has been considered in view of the Final Office Action that was mailed on July 2, 2010. Claims 18 and 29-34 are currently pending. By the present Amendment, Applicants have canceled claims 10-12, 14-17, 19-28, and 35, and amended claims 18 and 29. Applicants respectfully submit that the amendments to the claims effected herein do not introduce any new matter, are fully supported by the specification, and do not necessitate any further search of the prior art by the Examiner. In view of the following remarks and arguments, Applicants respectfully submit that each of pending claims 18 and 29-34 is allowable over the references of record, and accordingly, respectfully request reconsideration and allowance of these claims.

As an initial matter, Applicants highlight that the cancelation of claims 10-12, 14-17, 19-28, and 35 has been effected without prejudice in the interests of advancing prosecution. Applicants expressly reserve the right to re-present the subject matter of canceled claims 10-12, 14-17, 19-28, and 35 in one or more Continuation applications.

In the Final Office Action, claim 29 was objected to for informal reasons. Specifically, a typographical error in claim 29 was brought to Applicants' attention, and it was suggested that claim 29 be amended to recite "the attachment members . . ." rather than "that attachment members." (Emphases added).

By the present Amendment, Applicants have amended claim 29 in the manner suggested in the Final Office Action, and in view of this amendment, Applicants respectfully request withdrawal of the objection to claim 29.

Claims 10-12 and 19-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,403,326 to Harrison, *et al.* (hereinafter "Harrison") in view of U.S. Patent No. 6,165,183 to Kuehn, *et al.* (hereinafter "Kuehn").

As mentioned above, claims 10-12 and 19-23 have been canceled herein. Accordingly, Applicants respectfully submit that the rejection of claims 10-12 and 19-23 under 35 U.S.C. §103(a) over Harrison in view of Kuehn has been rendered moot, and respectfully request withdrawal of the rejection of these claims under 35 U.S.C. §103(a) over Harrison in view of Kuehn.

Claims 14-18, 24-28, and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harrison in view of Kuehn and U.S. Patent No. 5,762,613 to Sutton, *et al.* (hereinafter "Sutton").

As mentioned above, claims 14-17, 24-28, and 35 have been canceled herein. Accordingly, Applicants respectfully submit that the rejection of claims 14-17, 24-28, and 35 under 35 U.S.C. §103(a) over Harrison in view of Kuehn and Sutton has been rendered moot, and respectfully request withdrawal of the rejection of these claims under 35 U.S.C. §103(a) over Harrison in view of Kuehn and Sutton. With respect to claim 18, Applicants respectfully submit that the combination of Harrison, Kuehn, and Sutton fails to render the subject matter of independent claim 18 obvious, as presented herein.

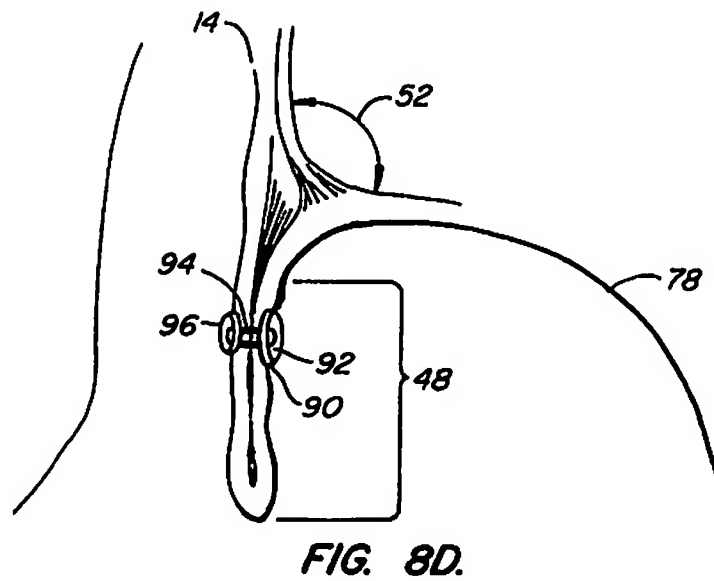
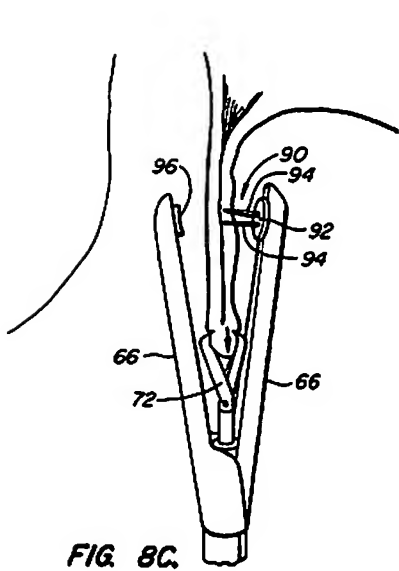
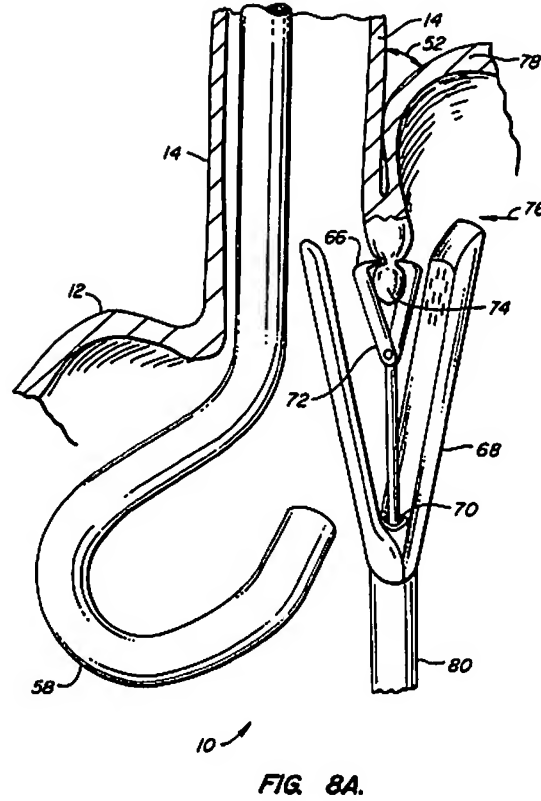
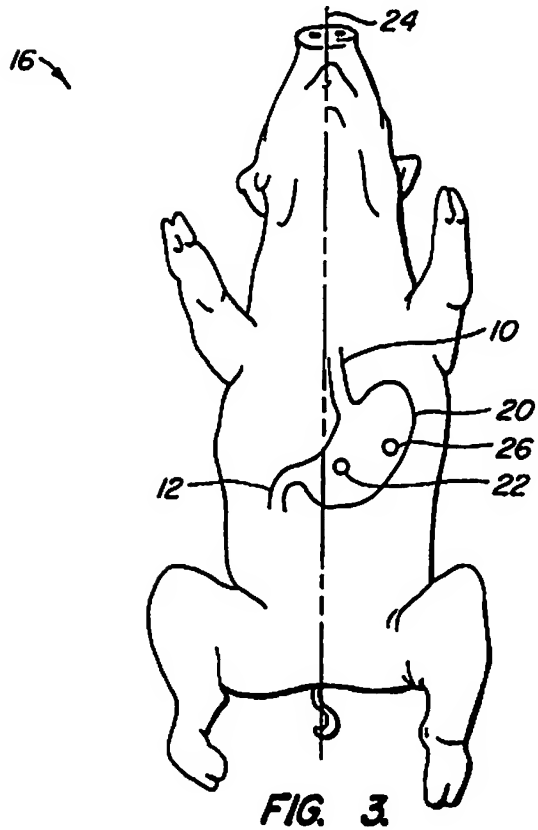
As a condition for patentability, 35 U.S.C. §103(a) indicates that "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter

as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art,” then the subject matter is not patentable. (Emphasis added).

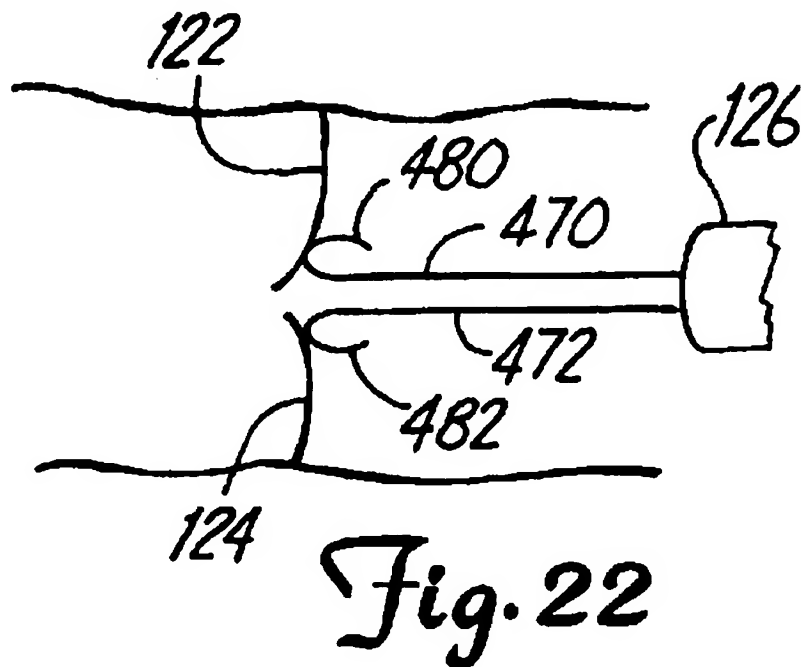
Amended independent claim 18 recites “[a]n apparatus for substantially closing a vascular opening in a vessel while permitting post operative blood flow through the vessel” that includes, *inter alia*, “a housing,” “an elongated shaft at least partially disposed in the housing,” “tissue engaging members disposed adjacent the distal end of the housing” and “adapted to cooperate to engage vascular tissue adjacent the vascular opening,” “jaw members connected to the housing and positioned adjacent the tissue engaging members . . . wherein at least one of the jaw members includes an attachment member,” and “an energy source connected to the attachment member to facilitate transmission of energy to the vascular tissue surrounding the vascular opening via the attachment member to thereby thermally fuse the vascular opening.” According to amended independent claim 18, “the attachment member is formed from a conductive material such that the attachment member is adapted to transmit energy received from the energy source to the vascular tissue surrounding the vascular opening to thereby thermally fuse the vascular tissue surrounding the vascular opening.”

Harrison relates to a method of fundoplication of a patient's stomach to the esophagus. (See col. 2, lines 43-44). In one embodiment of the disclosure, Harrison describes the placement of a flexible pediatric gastroscope 18 into the lumen 32 of a patient's stomach 20, which is angled anteriorly to transilluminate a site for a medial endoscopic port 22. (See col. 5, lines 12-15; FIG. 3 below). Subsequently, a stapler 68, which includes an internal grasper 72, is introduced through the port 22, and is positioned to grasp tissue at the gastroesophageal junction (GEJ). (See col. 6, line 61 – col. 7, lines 1, 38-44; FIG. 8A below). According to Harrison, the

jaws of the stapler 68 may be adapted to hold a tack 90. (See col. 8, lines 24-25; FIGS. 8C, 8D below).



Kuehn relates to “the repair of mitral and tricuspid valves exhibiting valve regurgitation,” and more particularly, “to apparatus and methods suitable for a less invasive repair of a mitral or tricuspid heart valve.” (Col. 1, lines 5-8). In one embodiment of the disclosure, Kuehn describes a cardiac catheter 126 through which hooks 470, 472 are deployed for grasping leaflets 122, 124 of the mitral valve. (See col. 10, lines 4-14; FIG. 22 below).



Sutton relates to “the field of medical diagnosis and treatment,” and more specifically, “to a forceps device having integrated optical fiber and remotely controllable biopsy forceps functions, and to the use thereof in medical diagnosis.” (Col. 1, lines 4-8). In one embodiment of the disclosure, Sutton describes forceps 10 that include a handle portion 12, a middle portion 14, a distal end 16 that includes opposed cutting jaws 80, 81. (See col. 3, lines 45-50; FIGS. 1, 2 below).

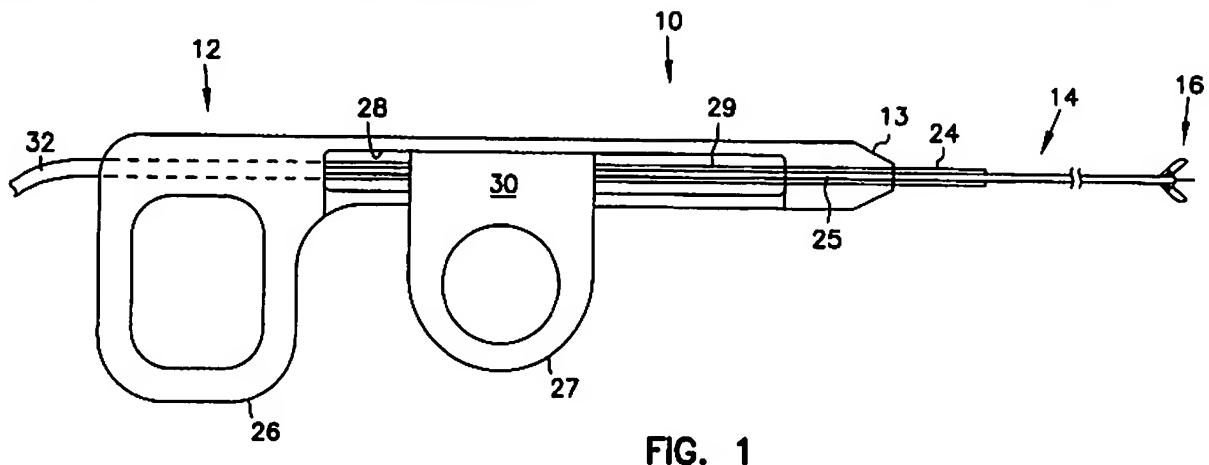


FIG. 1

The forceps 10 further include a main body with an inner tubular member 20, and an outer tubular member 22 that passes through a plastic sleeve 24, which serves as a reinforcing, strain relief member. (See col. 3, lines 51-55; see col. 4, lines 1-3; FIG. 1 above; FIG. 2 below).

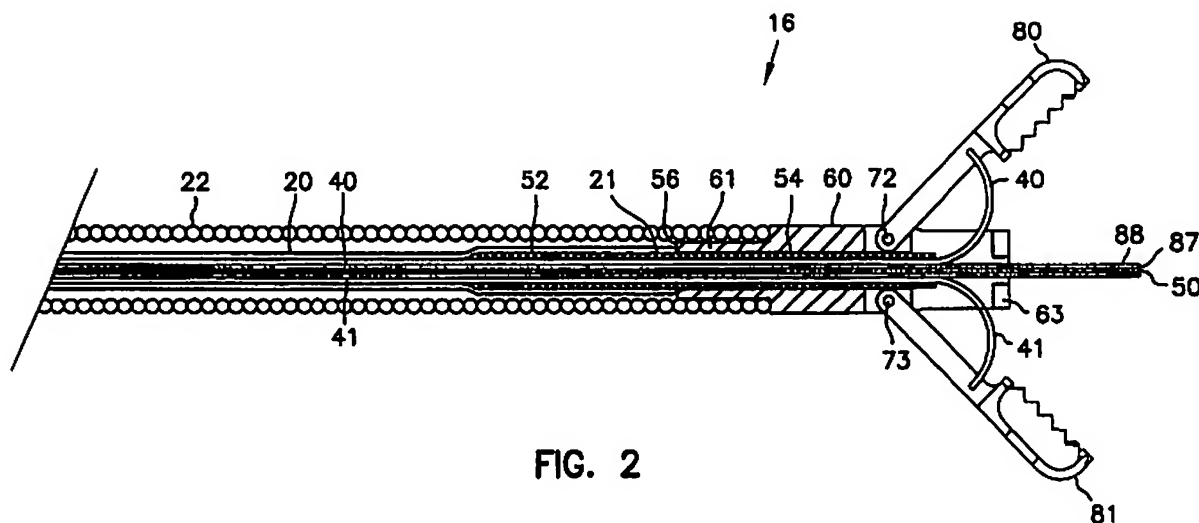


FIG. 2

As seen above in FIG. 2, a pair of control wires 40, 41, and an optical fiber 50 are positioned within the inner tube 20. (See col. 3, lines 64-65).

Continuing, Sutton discloses that the distal end 16 of the forceps 10 includes a yoke 60, which serves as a mounting member for the cutting jaws 80, 81. (*See* col. 4, lines 34-36; FIG. 2 above). The yoke 60 includes a proximal section, 61, a center section 62, and a distal section 63 with a vertical slot 70 that is dimensioned to allow for movement of the lever arms 85 supporting the jaws 80, 81. (*See* col. 4, lines 38-41, 62-64; FIGS. 5A, 5C below).

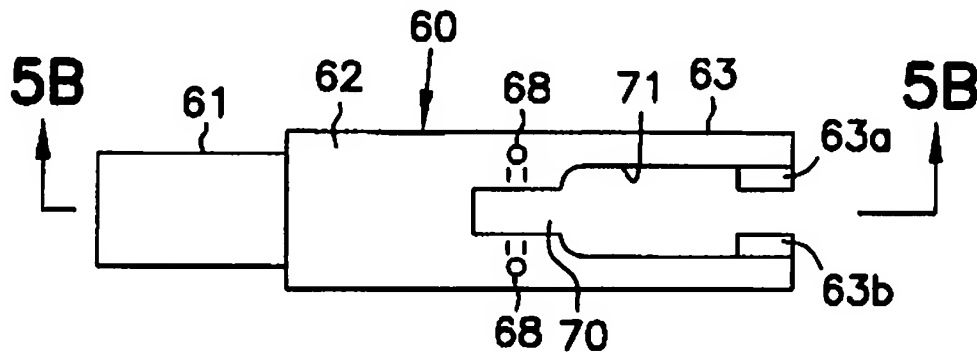


FIG. 5A

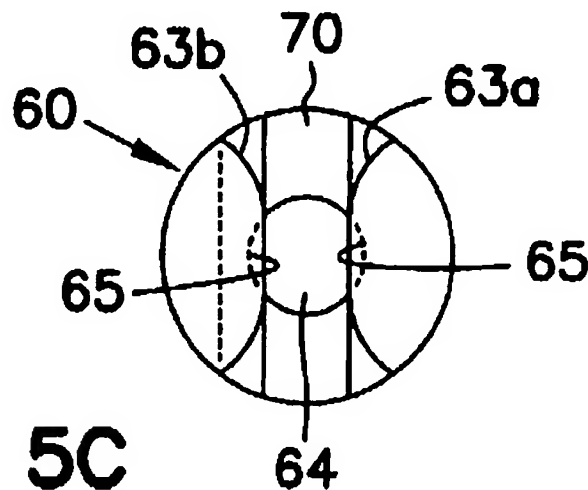


FIG. 5C

In the Final Office Action, the jaws of Harrison's grasper 72, the jaws of the stapler 68, and the tack 90 were respectively characterized as the "tissue engaging member," the "jaw members," and the "attachment member" recited in the claims. (*See* Final Office Action, pages

4, 7). While it was acknowledged that “Harrison fails to disclose the one or two tissue engaging members comprise two hooks or J-shaped configurations,” Kuehn was relied upon for disclosure of this concept with reference to the hooks 470, 472 seen above in FIG. 22. (*See* Final Office Action, pages 4-5). It was further acknowledged that neither Harrison nor Kuehn discloses an elongate shaft disposed within a housing, but Sutton was relied upon for disclosure of this concept with reference to the plastic sleeve 24 seen above in FIG. 1. (*See* Final Office Action, page 7).

Assuming, *arguendo*, that Harrison, Kuehn, and Sutton are properly combinable under the MPEP, Applicants highlight that Harrison fails to provide any specific information regarding the construction of the tack 90, or the materials used in the fabrication thereof.

Accordingly, Applicants respectfully submit that Harrison fails to disclose an “attachment member” that is “formed from a conductive material,” as recited in amended claim 18.

Moreover, neither Harrison, nor Kuehn, nor Sutton discloses, or even suggests, the use of an “energy source” in connection with the described devices, let alone, the connection of an “energy source” to an “attachment member” included on a “jaw member” of “[a]n apparatus for substantially closing a vascular opening in a vessel,” as also recited in amended independent claim 18. In fact, Applicants highlight that the tack 90 described in Harrison facilitates the mechanical attachment of adjacent tissue portions via the use of a foot 96, as seen above in FIG. 8D, rather than connection through the delivery of energy to the tissue “to thereby thermally fuse the vascular tissue surrounding the vascular opening,” as further recited in amended independent claim 18. (Emphasis added).

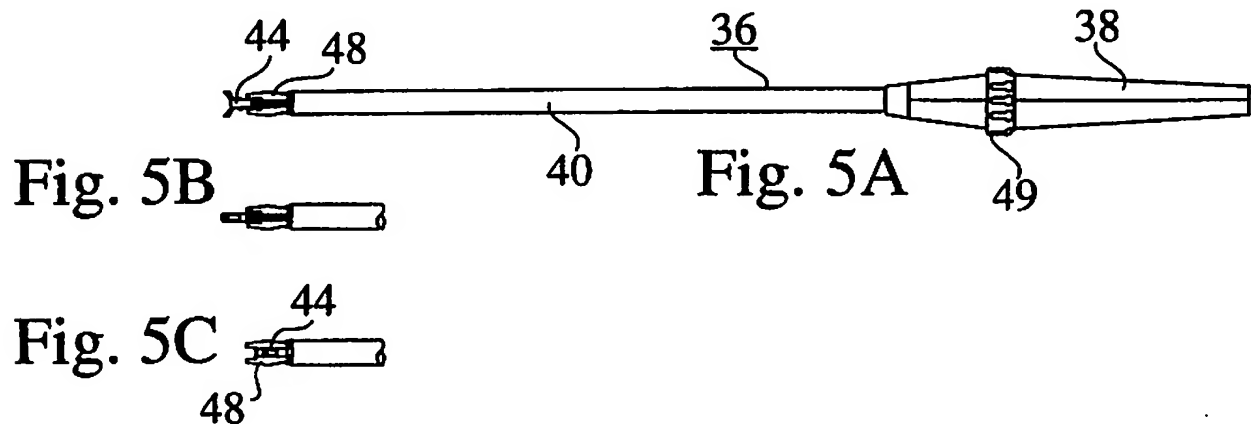
Accordingly, and for at least these reasons, *inter alia*, Applicants respectfully submit that the combination of Harrison, Kuehn, and Sutton fails to suggest the subject matter of amended independent claim 18 as a whole, and therefore, that the combination of Harrison, Kuehn, and Sutton fails to render the subject matter of amended independent claim 18 obvious. As such, Applicants respectfully submit that amended independent claim 18 is allowable over Harrison in view of Kuehn and Sutton under 35 U.S.C. §103(a).

Claims 29, 30, and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sutton in view of U.S. Patent No. 5,290,299 to Fain, *et al.* (hereinafter "Fain"). Applicants respectfully submit, however, that the combination of Sutton and Fain fails to render the subject matter of claims 29, 30, and 32 obvious.

Independent claim 29 recites "[a]n apparatus for substantially closing a vascular opening in a vessel" that includes "a housing," "an elongated shaft at least partially positioned within the housing, the elongated shaft defining a longitudinal axis and including a proximal end, a distal end, and a lumen extending between the proximal and distal ends," wherein the claimed "lumen" is "configured and dimensioned to receive a prepositioned guidewire such that the apparatus is movable along the guidewire," and the "elongated shaft" further includes recesses formed adjacent the distal end." Independent claim 29 further recites that the "apparatus" includes "tissue engaging members disposed adjacent the distal end of the housing," and "jaw members connected to the housing and positioned adjacent the tissue engaging members." According to amended independent claim 29, the "jaw members" include "attachment members depending inwardly therefrom towards the longitudinal axis" that are "configured and dimensioned to adjoin the tissue adjacent the vascular opening, that attachment members being further

configured and dimensioned for receipt by the recesses formed adjacent the distal end of the elongated shaft.”

Fain relates to “a method and apparatus for attaching implanted materials or devices to tissue inside the body.” (Col. 1 lines 9-11). In one embodiment of the disclosure, Fain describes a fastening tool 36 for use with fasteners 20, 22 that includes a handle 38, a shaft 40 that extends distally from the handle 38, a lever 42 that is carried by the handle 38 for actuating a first pair of jaws 44, and a trigger 46 that is also carried by the handle 38 for actuating a second pair of jaws 48. (See col. 4, lines 45-47; see col. 4, lines 67 – col. 5, line 4; FIGS. 1-4; FIGS. 5A-5C below).



In the Final Office Action, the middle portion 14 of Sutton’s forceps 10, the optical fiber 50, the vertical slot 70, and the control wires 40, 41 were respectively characterized as the “elongated shaft,” the “guidewire,” the “recesses,” and the “attachment members” recited in the claims. (See Final Office Action, page 8). Based upon this characterization, it was asserted that Sutton discloses “attachment members” that are “configured and dimensioned for receipt by the recesses in the elongated shaft.” (Final Office Action, page 8). While it was acknowledged that Sutton fails to disclose a “tissue engaging member,” Fain was relied upon for disclosure of this

concept with reference to the jaws 44 seen above in FIGS. 5A and 5C. (*See* Final Office Action, pages 8-9).

Applicants highlight that the structure identified by reference character 50 in the Sutton disclosure is an optical fiber, rather than “a guidewire.” (*See* col. 3, lines 64-65).

According to Sutton, the disclosed “[o]ptical fiber 50 extends through slider 30, and out of handle 12, in a protective cable or sheath 32, for connection to electro-optical units (not shown) which provide the illumination light to the fiber, and which receive and analyze the returned light from the target at distal the end of the forceps.” (Col. 4, lines 19-23) (emphasis added). Sutton fails to provide any indication, or suggestion, that the forceps 10 is “movable along” the optical fiber 50, as recited in independent claim 29, in any way, shape or form. The structure, and function, of the Sutton optical fiber 50 is simply different than that of the claimed “guidewire.”

Moreover, Applicants highlight that, according to Sutton, the control wires 40, 41, which, to reiterate, were characterized as the claimed “attachment members” in the Final Office Action (*see* Final Office Action, page 8), facilitate actuation of the jaws 80, 81. (*See* col. 4, lines 7-16). The control wires 40, 41 are not intended to come into contact with tissue during use of the disclosed device. Even if incidental contact between the control wires 40, 41 and the tissue were to occur, the control wires 40, 41 would not “adjoin the tissue adjacent the vascular opening,” and are not “configured and dimensioned” to perform this function.

Moreover, there is no disclosure in Sutton indicating, or even suggesting, that the control wires 40, 41 are ever positioned within the slot 70 provided at the distal section 63 of the yoke 60, which, to reiterate, was characterized as the claimed “recesses” in the Final Office Action. (*See* Final Office Action, page 8). As mentioned above, the vertical slot 70 accommodates

movement of the lever arms 85 supporting the jaws 80, 81, and does not receive the wires 40, 41.
(See col. 4, lines 62-64).

Accordingly, Applicants respectfully submit that Sutton fails to disclose, or even suggest, “attachment members” that depend inwardly from “jaw members,” and are “configured and dimensioned to adjoin the tissue adjacent the vascular opening, that attachment members being further configured and dimensioned for receipt by the recesses formed adjacent the distal end of the elongated shaft,” as recited in independent claim 29. (Emphasis added).

Even if it is assumed, *arguendo*, that the characterization of Fain proffered in the Final Office Action is accurate, and that Sutton and Fain are properly combinable under the MPEP, including the “tissue engaging members” purportedly disclosed in Fain would fail to cure the aforescribed deficiencies in Sutton.

Accordingly, and for at least this reason, *inter alia*, Applicants respectfully submit that the combination of Sutton and Fain fails to suggest the subject matter of independent claim 29 as a whole, and therefore, that the combination of Sutton and Fain fails to render the subject matter of independent claim 29 obvious. As such, Applicants respectfully submit that independent claim 29 is allowable over Sutton in view of Fain under 35 U.S.C. §103(a). Since claims 30 and 32 depend directly and indirectly from independent claim 29, respectively, and include each element recited therein, for at least the reasons that independent claim 29 is allowable over Sutton in view of Fain under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claims 30 and 32 are also allowable over Sutton in view of Fain under 35 U.S.C. §103(a).

Claims 31, 33, and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sutton and Fain, as applied to claim 29 above, in further view of Kuehn. Applicants respectfully

submit, however, that the combination of Sutton, Fain, and Kuehn fails to render the subject matter of claims 31, 33, and 34 obvious.

In the Final Office Action, it was acknowledged that the combination of Sutton and Fain fails to disclose “two tissue engaging members comprise [*sic*] two hooks or a J-shaped configuration disposed in general diametrical opposed relation in the advanced position, wherein the engaging members are composed of a shape memory alloy,” as substantially recited in claims 31, 33, and 34, but Kuehn was relied upon for disclosure of this concept in combination with elements allegedly known in the art, i.e., shape memory materials. (*See* Final Office Action, pages 9-10).

Even if it is assumed, *arguendo*, that the characterization of Kuehn proffered in the Final Office Action is accurate, and that Sutton, Fain, and Kuehn are properly combinable under the MPEP, incorporating the “tissue engaging members” purportedly disclosed in Kuehn would fail to remedy the aforescribed deficiencies in the combination of Sutton and Fain.

Accordingly, and for at least this reason, *inter alia*, Applicants respectfully submit that the combination of Sutton, Fain, and Kuehn fails to suggest the subject matter of independent claim 29 as a whole, and therefore, that the combination of Sutton, Fain, and Kuehn fails to render the subject matter of independent claim 29 obvious. As such, Applicants respectfully submit that independent claim 29 is allowable over Sutton in view of Fain and Kuehn under 35 U.S.C. §103(a). Since claims 31, 33, and 34 depend indirectly from independent claim 29, and include each element recited therein, for at least the reasons that independent claim 29 is allowable over Sutton in view of Fain and Kuehn under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claims 31, 33, and 34 are also allowable over Sutton in view of Fain and Kuehn under 35 U.S.C. §103(a).

Claims 10-12 and 14-35 were also rejected on the ground of non-statutory obviousness-type double patenting over claims 1-9 of U.S. Patent No. 6,248,124 (hereinafter "the '124 patent"), claims 1-25 of U.S. Patent No. 6,676,685 (hereinafter "the '685 patent"), and claims 1-6 of U.S. Patent No. 7,252,666 (hereinafter "the '666 patent").

As mentioned above, claims 10-12, 14-17, 19-28, and 35 have been canceled herein. Accordingly, Applicants respectfully submit that the rejection of claims 10-12, 14-17, 19-28, and 35 on the ground of non-statutory obviousness-type double patenting over claims 1-9 of the '124 patent, claims 1-25 of the '685 patent, and claims 1-6 of the '666 patent has been rendered moot, and respectfully request withdrawal of the double patenting rejections of these claims.

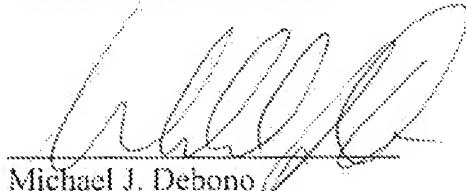
With respect to claims 18 and 29-34, Applicants respectfully request reconsideration of the aforementioned double patenting rejections in view of the amendments to the claims effected herein. Upon such review, should it be determined that the aforementioned double patenting rejections are appropriate, upon the indication that claims 18 and 29-34 are otherwise allowable, Applicants will execute a terminal disclaimer with respect to claims 1-9 of the '124 patent, claims 1-25 of the '685 patent, and claims 1-6 of the '666 patent in the interests of advancing prosecution.

In view of the foregoing remarks and arguments, Applicants respectfully submit that claims 18 and 29-34 are allowable over the references of record, and accordingly, respectfully request reconsideration and allowance of these claims.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, or resolve any outstanding matter, the Examiner is sincerely invited to contact Applicants' undersigned representative at the number indicated below.

Please charge any deficiency, as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required, and charge Deposit Account No. 21-0550 accordingly.

Respectfully submitted,



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